DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRICT

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106
Telephone: 215-597-4390

m2248n

WARNING LETTER

99-PHI-06

November 30, 1998

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Chris M. Mellott
P.O. Box 341
12271 Sylvan Drive
Mercersburg, Pennsylvania 17236

Dear Mr. Mellott:

On July 13, 1998 Food and Drug Administration (FDA) Investigator Gregory E. Beichner conducted an inspection of your livestock dealing/buying operation located at 12271 Sylvan Drive in Mercersburg, Pennsylvania, in response to a United States Department of Agriculture (USDA) report regarding an illegal drug residue in a cow you offered for sale and slaughter for human food. Additional investigation by the FDA at [redacted] and [redacted] has revealed serious violation of Sections 402(a)(2)(C)(i)(i) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about March 31, 1998, you offered a cow, back tag #4272, for sale for slaughter as human food at [redacted] The subject cow was purchased by [redacted] on March 31, 1998 and was subsequently slaughtered for human food on April 1, 1998 at [redacted] USDA testing revealed the presence of 0.29 parts per million (ppm) erythromycin in the kidney tissue of your animal. The tolerance for erythromycin in edible bovine tissue is 0.10 ppm. The presence of erythromycin in the kidney tissue from your animal at the concentration level detected renders the food from the animal to be adulterated.

Our investigation also found that you hold animals under conditions that permit those bearing potentially harmful drug residues to enter the food supply. For example, you lack an adequate system for assuring that animals have been treated with drugs which have been approved for use in those species; for

assuring that drugs are used in a manner not contrary to the directions contained in the labeling; and for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Food from animals held under such conditions is adulterated.

The offering of animals for slaughter for human consumption which contain illegal drug residues is a violation of the Act. Part of your responsibility is to assure that all animals offered from your facility are free of drugs to prevent tissue residues.

A person who causes an animal with an illegal drug residue to be sold for human food may be subject to regulatory action such as seizure and/or injunction. This applies to anyone in the chain of handling an animal including the producer, livestock dealer, livestock hauler, auctionhouse, and the slaughterhouse. It is important that the consumer be protected from excessive intake of drug residues in the food supply.

The above is not intended as an all-inclusive list of violations. As a producer of animals which are offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused or participated in causing the adulteration of an animal that was offered for sale to a slaughterhouse that ships beef in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within 15 days of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen working days, state the reasons for the delay and the timeframe in which correction will be achieved.

Your reply should be directed to the attention of James C. Illuminati, Compliance Officer, at the above address.

Sincerely,

Marguerite E. Eagan

Marguerite E. Eagan
Acting District Director
Philadelphia District

jci

cc: Dr. John I. Enck, Director
PA State Bureau of Animal Industry
Agriculture Building
2301 North Cameron Street
Harrisburg, PA 17120

cc: Food Safety and Inspection Service (FSIS)
106 South 15th Street
Suite 904
Omaha, Nebraska 68102
Attention: Residue Staff